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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/331,262 07/13/99 PEREGRINO FERREIRA P 41826

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HM12/0612

EXAMINER

ZEMAN, R

ART UNIT	PAPER NUMBER
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1645

10

DATE MAILED:

06/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/331,262

Applicant(s)
Ferreira Et. Al.

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Apr 21, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Response to Amendment

Amendment filed on April 21, 2000 is acknowledged. Claims 1-3 were amended.

Claims 1-3 are pending and under consideration.

Objections to Specification

The objections to the disclosure are withdrawn in light of the amendments thereto.

Claim Objections

The objection to claim 1 for the improper use of the term "unbounded" is withdrawn in light of the amendments thereto.

Claim Rejections Withdrawn

The rejection of Claims 1-3 under U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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claimed invention is withdrawn. Applicant's arguments have been considered and found persuasive.

The rejections of Claims 2 and 3 under U.S.C. 112 second paragraph, as being indefinite are withdrawn in light of the amendments to the claims.

Claim Rejections Maintained and New Grounds of Rejections:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 1 under U.S.C. 112 second paragraph, as being vague and indefinite is maintained. Claim 1 still uses the terms "protein" and "antigen" interchangeably. It is unclear whether the limitations of the claim is drawn to the ^{use of} entire p26 protein or merely an antigenic epitope.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-3 are rejected under 35 U.S.C. 103(a) for reasons of record.

The rejection of Claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (U.S. Patent 4,806,467) and Shen et al. (American Journal of Veterinary Research Vol 45(8) pp 1542-1543) in view of Peterson et al. (U.S. Patent 5,427,907) and Reis et al. (Reis et al, 1996 GENBANK ACC. NO.U53452) is maintained for reasons of record. Applicant argues that, while the assay disclosed by Peterson et al. is similar to the claimed invention, said assay utilizes gp45 not p26. Additionally, Peterson et al. doesn't suggest the use of p26 due to the likelihood of false positive results. Applicant further argues that, while the assays disclosed by Porter et al. and Shen et al. do use the p26 core protein, it is obtained from live viral cultures and, hence, is unstable. Applicant then argues that there is antigenic variation between the gp45 used by Peterson et al. and other envelope proteins since the EIA virus presents antigenic variation especially in its envelope proteins and that Peterson et al. proposed the use of synthetic peptides against only one antigenic epitope. Applicant then infers that the recombinant p26 has more antigenic epitopes and that confers "unexpected" benefits including the ability to use it at a higher concentration and resolving false negative results by its ability to bind more protein on the solid supports. Applicant concludes by arguing that the fact that the claimed invention is "quicker and easier" than other EIA assays is another unexpected result and that while a person skilled in the art might think to try an assay similar to the claimed invention, the advantages of the claimed invention could not have been predicted. These arguments have been considered and are not deemed to be persuasive.

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With regard to Applicant's argument that Peterson et al doesn't suggest the use of p26 due to "the likelihood of false positive results", Peterson et al. specifically state " the amino acid sequence of the peptide of the present invention comprises any sequence which corresponds to that of an antigenic site on the virus, and preferably located in the envelope protein portion of the equine infectious anemia virus". Peterson et al. use recombinant proteins in their assay to reduce false positive results due to the extraneous proteins that are inherent in isolating EIA viral proteins from live viral cultures. Additionally, in response to Applicant's argument that it would have been "obvious to try" for one of skill in the art to use a recombinant p26 protein in the methods of Peterson et al., one of skill in the art would have a reasonable expectation of success since, as Applicant has pointed out on page 4 of his amendment, " the p26 antigen (protein) is a well-known and well-characterized material" and "those skilled in the art well know how to make the material necessary for practice of the present method" Applicant's argument that the p26 protein used by Shen et al. and Porter et al. were "unstable" since they were derived from live viral cultures only bolsters Examiner's position that one would have been motivated to use the recombinant form of the protein in assays that used the native p26 protein.

Applicant's assertion that the increased sensitivity of the assay when using recombinant p26; its increased binding to solid supports and the ability to use recombinant p26 at a higher concentration were "unexpected results" is not supported by factual evidence. Applicant does not show side by side comparisons of native and recombinant p26 proteins when used in the same assay and consequently has presented no factual basis for this assertion. Additionally, increased

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sensitivity, reduction of false positive results, ability to use the protein at higher concentrations with a greater ease of use are all benefits of using **any** recombinant protein as opposed to a native protein since recombinant protein preparations do not have the extraneous proteins inherent in native protein preparations.

The use of recombinant proteins in conventional assays is common practice and hence would have been obvious to one of skill in the art. Finally, Applicant is reminded that the aforementioned rejections are based on the combination of references, not only Peterson et al.

Conclusion

No Claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Anthony Caputa, can be reached at (703)308-3995.


DONNA WORTMAN
PRIMARY EXAMINER